

# Coronavirus Disease 2019 (COVID-19)

## Serology Testing for COVID-19

CDC has developed a laboratory blood test to assist with efforts to determine how much of the U.S. population has been infected with SARS-CoV-2, the virus that causes COVID-19. CDC is also using its serologic test (antibody) to evaluate the performance of commercial antibody tests.

An antibody test looks for the presence of antibodies, which are specific proteins made in response to infections. Antibodies can be found in the blood of people who are tested after infection and show that people have had an immune response to the infection. Antibody test results are especially important for detecting previous infections with few or no symptoms.

However, we do not know if the antibodies that result from SARS-CoV-2 infection will provide someone with immunity from a future infection. If antibodies do provide immunity, we don't know what titer or amount of antibodies would be protective or the duration that protection would last. CDC scientists are conducting studies to better understand the level of antibodies needed for protection, the duration of that protection, and the factors associated with whether a person develops a protective antibody response.

CDC's serologic test has been designed and validated for broad-based surveillance and research purposes, to provide information needed to guide the response to the pandemic and protect the public's health. This test is not currently designed for individual use, i.e., to test people who want to know if they have been previously infected with SARS-CoV-2.

### CDC is evaluating the performance of commercial antibody tests




Commercially manufactured antibody tests check for SARS-CoV-2 antibodies in individuals and are available through healthcare providers and commercial laboratories. CDC is evaluating the performance of these tests in collaboration with the following federal organizations:

- Biomedical Research and Development Authority
- U.S. Food and Drug Administration (FDA)
- National Institutes of Health
- Department of Defense
- White House Office of Science and Technology Policy



Results from the initial federal evaluation are expected in May and will be updated as more tests are evaluated.

Antibody tests designed to provide results to individuals or healthcare providers can show whether someone was previously infected with SARS-CoV-2. However, these tests have limitations. Specificity (doesn't detect non-target viruses) and sensitivity (true positive rate) of antibody tests vary.

Antibody test results should not be used to diagnose someone with an active SARS-CoV-2 infection. It typically takes 1 to 3 weeks after someone becomes infected with SARS-CoV-2 for their body to make antibodies; some people may take longer to develop antibodies. Depending on when someone was infected and the timing of the test, the test may not find antibodies in someone with an active infection. A [test that detects the SARS-CoV-2 virus](#), such as one that checks respiratory samples, should be used to test for active infection.

- [Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy](#) 
- Check FDA's website to see [antibody tests with emergency use authorization](#)  FDA has reviewed the validation of these tests.
- Read FDA's letter to healthcare providers: [Important Information on the Use of Serological \(Antibody\) Tests for COVID-19](#) 

## About CDC's serologic test

CDC's serologic test is based on a set of [serologic tests that CDC developed and optimized](#)  to detect SARS-CoV-2 antibodies in serum, which is a component of blood. These tests use live virus (isolated by CDC in February 2020) and a specific SARS-CoV-2 protein, the spike antigen (designed and produced by the [Vaccine Research Center](#)  at the National Institutes of Health).

CDC's serologic test is designed to detect antibodies produced in response to SARS-CoV-2 and to avoid detection of antibodies against other common coronaviruses that cause less severe illnesses, such as colds.

CDC's test has a specificity of greater than 99% and a sensitivity of 96% based on initial tests. It can be used to identify past SARS-CoV-2 infection in people who were infected at least 1 to 3 weeks previously.

## CDC serology surveillance strategy

CDC has a strategy for using antibody testing as part of surveillance efforts to better understand how much of the U.S. population has been infected with SARS-CoV-2 and how the virus is spreading through the population over time.

### Additional Resources

[FAQs for Laboratories: Serology](#)

[Viral Testing Tools and Virus: Questions and Answers](#)

[Testing for COVID-19](#)

[FDA: Serology/Antibody Test FAQs](#) 